

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 29/00		A1	(11) International Publication Number: WO 97/27898 (43) International Publication Date: 7 August 1997 (07.08.97)									
<p>(21) International Application Number: PCT/US97/01468</p> <p>(22) International Filing Date: 31 January 1997 (31.01.97)</p> <p>(30) Priority Data:</p> <table> <tr> <td>60/010,614</td> <td>2 February 1996 (02.02.96)</td> <td>US</td> </tr> <tr> <td>08/730,327</td> <td>11 October 1996 (11.10.96)</td> <td>US</td> </tr> <tr> <td>08/730,496</td> <td>11 October 1996 (11.10.96)</td> <td>US</td> </tr> </table> <p>(71) Applicant (for all designated States except US): TRANSVASCULAR, INC. [US/US]; 1505 - D Adams Drive, Menlo Park, CA 94025 (US).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): EVARD, Philip, C. [US/US]; 3192 Bryant Street, Palo Alto, CA 94306 (US). FLAHERTY, J., C. [US/US]; 766 La Prenda Road, Los Altos, CA 94024 (US). GARIBOTTO, John, T. [US/US]; 6284 Lido Court, Newark, CA 94560 (US). MACAULAY, Patrick, E. [US/US]; 3268 Flintview Court, San Jose, CA 95148 (US). MACHOLD, Timothy, R. [US/US]; 65 Bernal Avenue, Moss Beach, CA 94038 (US). MAKOWER, Joshua [US/US]; 177 Yerba Buena Avenue, Los Altos, CA 94022 (US). WHITT, Jason, B. [US/US]; 2616 Leavenworth Street, San Francisco, CA 94133 (US). ROTH, Alex,</p>		60/010,614	2 February 1996 (02.02.96)	US	08/730,327	11 October 1996 (11.10.96)	US	08/730,496	11 October 1996 (11.10.96)	US	<p>T. [US/US]; 1354 Regent Street, Redwood City, CA 94061 (US).</p> <p>(74) Agents: BUYAN, Robert, D. et al.; Stetina Brunda & Buyan, Suite 401, 24221 Calle de la Louisa, Laguna Hills, CA 92653 (US).</p> <p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p>	
60/010,614	2 February 1996 (02.02.96)	US										
08/730,327	11 October 1996 (11.10.96)	US										
08/730,496	11 October 1996 (11.10.96)	US										
<p>Published</p> <p><i>With international search report.</i></p> <p><i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>												
<p>(54) Title: METHODS AND APPARATUS FOR CONNECTING OPENINGS FORMED IN ADJACENT BLOOD VESSELS OR OTHER ANATOMICAL STRUCTURES</p> <p>(57) Abstract</p> <p>This invention is methods and apparatus for connecting two anatomical passageways, such as blood vessels, in side-to-side fashion. Openings are formed in the sidewalls of the passageways, and a connector apparatus (10) of the present invention is implanted within such openings, and extends between the passageways or blood vessels (BV1, BV2) so as to connect the passageways or blood vessels (BV1, BV2) such that the openings are held in direct alignment with one another, thereby allowing body fluids to pass from one passageway into the other.</p>												

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

-1-

**METHODS AND APPARATUS FOR CONNECTING OPENINGS FORMED IN
ADJACENT BLOOD VESSELS OR OTHER ANATOMICAL STRUCTURES**

Related Applications

5 This patent application claims priority to United States Provisional Patent Application Serial No. 60/010,614, filed on February 2, 1996, and is a continuation-in-part of co-pending United States Patent Applications 08/730,327, filed on October 11, 1996 and 10 08/730,496, filed on October 11, 1996, the entire disclosure of each such related application being expressly incorporated herein by reference.

Field of the Invention

15 The present invention relates generally to medical devices, and more particularly to methods and apparatus for making connections between blood vessels or other adjacently situated anatomical or synthetic structures having hollow lumens or cavities formed therein.

20

Background of the Invention

25 In modern medical practice, it is often desirable to form connections between adjacent anatomical passageways, or between adjacent segments of a single anatomical passageway. The types of anatomical passageways between which such connections may be made include; blood vessels, vas deferens, fallopian tubes, intestines, lymphatic ducts, grafts, ventricular cavities of the heart or brain, etc.

30 Recently, applicant has devised certain in situ vascular bypass procedures wherein blood flow passageways (e.g., puncture tracts or interstitial tunnels) are formed between the lumens adjacently situated blood vessels (e.g., between an obstructed coronary artery and an adjacent coronary vein) to bypass a diseased, injured or obstructed segment of one blood vessel. These procedures have previously been

-2-

described in United States Patent Application Serial Nos. 08/730,327 and 08/730,496. Also, Provisional United States Patent Application Serial No. 60/010,614 particularly describes certain minimally invasive 5 vascular grafting procedures devised by applicant for by-passing an obstructed artery. In these grafting procedures, a tubular graft (e.g., a segment of an endogenous blood vessel or a tube graft formed of natural or synthetic material) is maneuvered into 10 juxtaposition with the obstructed artery. One or more openings are formed in the graft and the adjacent artery. The openings formed in the graft are then connected to the openings formed in the artery, such that blood may flow between the graft and the artery. 15 Additionally, various procedures have been reported by others wherein implantable apparatus are used to connect or facilitate flow of bodily fluid between anatomical passageways (e.g., genitourinary ducts). One such procedure is described in United 20 States Patent No. 3,042,021 (Read) entitled BYPASS TYPE INSERT PLUG FOR BODY PASSAGEWAY.

To facilitate the connection of adjacently situated anatomical structures, as in the above-mentioned medical procedures, there exists a need in 25 the art for the design and development of new connector apparatus which may be implanted, through transluminal catheters or probes, to form a secure connection between openings formed in adjacently situated anatomical structures and/or to maintain such openings 30 in direct alignment and/or fluidic communication with each other.

Summary of the Invention

The present invention provides apparatus for 35 connecting or joining a first opening formed in a first anatomical structure of the type having a hollow inner space or lumen (e.g., a blood vessel, a hollow organ, a

-3-

chamber of the heart, a vascular graft, etc.) with a second opening formed in a second anatomical structure which also has a hollow innerspace of similar type. In general, these connecting apparatus comprise a) a first 5 engagement member which is engageable with the first anatomical structure, b) a second engagement member which is engageable with the second anatomical structure, and c) a connecting portion which extends or traverses between the first and second engagement members, and serves to hold the openings formed in the 10 first and second anatomical structures in the desired alignment, typically, such that fluid may pass from one anatomical structure into the other.

Further in accordance with the invention, the 15 connecting apparatus may be initially deployable in a radially compact state such that it may be advanced transluminally through the body to a desired implantation site, and is subsequently transitionable to a radially expanded configuration wherein the first 20 engagement member will engage the first anatomical structure and the second engagement member will engage the second anatomical structure. Additionally or alternatively, the first and second engagement members may be initially deployed in non-operative positions 25 (e.g., extending generally parallel to the longitudinal axis of the apparatus) to facilitate transluminal passage and/or placement of the apparatus at the desired implantation site. Thereafter, the first and second engagement members may be transitionable to a 30 second configuration (e.g., an outwardly splayed configuration) such that the first and second engagement members will engage the first and second anatomical structures, as desired. In this manner, the apparatus may be self expanding or self splaying (e.g., 35 formed of resilient or shape memory material) such that the radial expansion or transitioning of the engagement members will occur when surrounding constraint (e.g.,

-4-

constraint of a surrounding catheter wall) has been removed from the apparatus. Alternatively, the apparatus may be plastically deformable and provided with a pressure-exerting tool (e.g., a balloon) which 5 will plastically deform the apparatus to cause the desired radial expansion and/or transitioning of the engagement members after the apparatus has been positioned in its desired implantation site.

Further in accordance with the invention, the 10 engagement members may comprise wire loops, wire members, flanges, extensions, tongues, or any other suitable type of member which will embed into or otherwise engage the adjacent surface of an anatomical structure so as to hold the apparatus at its desired 15 implantation site and/or to maintain the patency of the passageway as well as the length of the connection.

Still further in accordance with the invention, the connecting portion of the apparatus may comprise one or more elongate strands or members, a solid or 20 perforated tube, or any other suitable connecting portion which will serve to link or connect the first and second engagement members and hold them at their desired spaced-apart distance. In some embodiments, the connecting portion may be elastic or biased so as 25 to exert continual pulling force or retraction against the first and second engagement members. In other embodiments, the connecting portion may be rigid and non-elastic so as to remain at a fixed non-alterable length. Additionally, in some embodiments, the 30 connecting portion may define a cylindrical or annular support member which will dilate, support or otherwise maintain any surrounding interstitial tissue in a desired configuration so as to prevent blockage or non-patency of the flow path formed between the first and 35 second openings in the first and second anatomical structures.

-5-

Additionally, the connecting portion may be constructed to maintain a minimum passageway diameter between the openings in the first and second anatomical structures. Also, the connecting portion may be 5 constructed to perform some surface modeling or customization of the surrounding tissue as by mechanical pressure exertion, application of a coating or chemical treatment, xenograft, emission of energy, etc. In this manner, the delivery catheter or delivery 10 system used to facilitate implantation of the correct connector apparatus may be equipped with wires, or other energy transmitting members which are in contact with the connector apparatus and which will deliver energy into the connector apparatus, thereby using the 15 connector apparatus as an energy-transferring member for causing deburring, enlargement, scaring, or other modification of the surrounding tissue with which the connector member comes in contact. Examples of the types of energy which may be useable for this purpose 20 include electrical energy, radiofrequency, ultrasound, radiation (e.g., beta, gamma, etc.), etc.

Still further in accordance with the invention, the connecting portion of the apparatus may be elastic, adjustable, telescoping, distendible or of accordion 25 construction, etc., so as to adjust or conform to passageways of differing length. This aspect of the invention will allow a connector apparatus to be used for applications wherein the distance between the first and second openings in the first and second 30 anatomical structures may vary and in each specific application, to maintain the first and second anatomical structures in relatively constant tension (i.e., constant force). Alternatively, for connector apparatus which do not incorporate such longitudinal 35 elasticity, adjustability, telescoping, distensible or accordion configuration, the connector apparatus may be provided in a variety of different lengths and the

-6-

operator may select the appropriate length of the connector apparatus prior to installation.

Still further in accordance with the invention, the leading edge of the apparatus may be a sharpened 5 cutting edge or may be otherwise adapted to cut or sever tissue, such that the delivery and advancement of the apparatus through the openings in the anatomical structures and/or the passageway created therebetween may further serve to form such openings or passageway, 10 or to enlarge, customize, model or otherwise alter the tissue with which it comes in contact.

Still further in accordance with the invention, there are provided connector apparatus having a connecting portion which comprises legs or members 15 which penetrate through tissue surrounding the openings formed in the anatomical structures and/or any intervening tissue located therebetween, such that the connecting portion of the apparatus is embedded within the host tissue and is actually located outside of the 20 channel or passageway formed between the first and second openings in the first and second anatomical structures.

Still further in accordance with invention, there are provided delivery systems and devices for 25 delivering and implanting the connector apparatus of the present invention. These delivery apparatus and devices are typically incorporated into or mounted upon a transluminally advanceable catheter, and comprise a retractable sheath, inflatable balloon, push rod, 30 alter-apposing slider sheaths, or rotatable members which operate to radially expand or advance the connector apparatus into its desired implantation position within the body.

These and other elements and objects of the 35 present invention will be more fully understood and appreciated upon reading of the detailed description of preferred embodiments set forth herebelow, and studying

-7-

of the accompanying drawings wherein the preferred embodiments are shown.

Brief Description of the Drawings

5 Figure 1 is a partial longitudinal sectional view of two adjacently positioned blood vessels having a blood flow passageway formed therebetween, and a connector apparatus of the present invention implanted within such blood flow passageway to facilitate and
10 maintain the desired side-to-side connection between the blood vessels.

Figure 2 is a perspective view of a coil-type connector apparatus of the present invention.

15 Figure 2' is a perspective view of a modified coil-type connector apparatus of the present invention.

Figure 2'' is a perspective view of another modified coil-type connector apparatus of the present invention having a tubular mid portion.

20 Figure 2''' is a perspective view of another coil-type connector apparatus of the present invention having a fused mid-portion.

25 Figure 2'''' is a side elevational view of a helical coil connector apparatus of the present invention which is biased to a longitudinally collapsed configuration.

Figure 3 is a perspective view of a mesh type connector apparatus of the present invention.

30 Figure 3' is a perspective view of a mesh type connector apparatus of the present invention having optional engagement members formed on either end thereof.

Figure 3'' is a perspective view of the mesh type connector apparatus of Figure 3' wherein the engagement members are self-splaying.

35 Figure 3''' is a perspective view of the mesh type connector apparatus of Figure 3' wherein the engagement members are pressure-splayable, and wherein the

-8-

apparatus is shown in conjunction with a pressure-exerting balloon catheter which is useable to splay the engagement members at the desired implantation site.

5 Figure 4 is a perspective view of a tube type connector apparatus of the present invention.

Figure 4' is a perspective view of a tube type connector apparatus of the present invention having optional engagement members formed on either end thereof.

10 Figure 4'' is a perspective view of the tube type connector apparatus shown in Figure 4', wherein the engagement members are self-splaying.

15 Figure 4''' is a perspective view of the tube type connector apparatus shown in Figure 4', wherein the engagement members are pressure-splayable, and wherein the apparatus is shown in conjunction with a pressure-exerting balloon catheter which is useable to cause splaying of the engagement members at the desired implantation site.

20 Figure 5 is a perspective view of a cylindrical connector apparatus of the present invention comprising a solid (non-perforated) tube member having optional engagement members formed on either end thereof.

25 Figure 5' is a perspective view of a non-hyperbolic, cylindrical connector apparatus wherein the engagement members are self-splaying.

30 Figure 5'' is a perspective view of a cylindrical connector apparatus wherein engagement members are pressure-splayable, and wherein the apparatus is shown in conjunction with a pressure-exerting balloon-catheter which is usable to cause splaying of the engagement members at the desired implantation site.

35 Figure 5''' is a perspective view of a cylindrical connector apparatus wherein the tube member is formed of wire mesh having a multiplicity of openings or perforations formed therein, and multiple engagement members are formed on both ends of the tube member;

-9-

Figure 5'''' is a perspective view of a cylindrical connector apparatus wherein the tube member is formed of wire mesh having a multiplicity of openings or perforations formed therein, and two (2) engagement members are formed on each end of the tube member, said engagement members being in direct alignment with one another;

5 Figure 5''''' is a perspective view of a cylindrical connector apparatus wherein the tube member is formed of a solid tube, and wherein engagement members comprising semi-circular wire projections are mounted on either end of the tube member;

10 Figure 6 is a perspective view of a two-piece rivet-type connector apparatus of the present invention having a first rib-in-groove connection system formed thereon.

15 Figure 6' is a perspective view of an alternative two-piece rivet-type connector apparatus of the present invention having a tapered friction-fit engagement system formed thereon.

20 Figure 6'' is a perspective view of another alternative two-piece rivet-type connector apparatus of the present invention having a second rib-in-groove or magnetic type engagement system formed thereon.

25 Figure 7a is a top plan view of a first elastomeric connector apparatus of the present invention comprising a tubular mid-portion having elastomeric engagement members formed at either end thereof.

30 Figure 7a' is a perspective view of the elastomeric connector apparatus of Figure 7a.

35 Figure 7b is a top plan view of another elastomeric connector apparatus of the present invention comprising a tubular mid portion having a non-circular lumen and engagement flanges formed at either end thereof.

-10-

Figure 7b' is a perspective view of the connector apparatus shown in Figure 7b.

Figure 7c is a perspective view of a connector apparatus of the present invention comprising an 5 elastomeric body having wire support members formed therein.

Figure 7d is a perspective view of a wire connector apparatus of the present invention.

Figure 7d' is a perspective view of the wire 10 connector apparatus of Figure 7d having a cylindrical elastomeric or fabric sleeve formed thereon.

Figure 7d'' is a perspective view of another wire connector apparatus formed of two of the connector apparatus of Figure 7d, coupled together to form a 15 singular apparatus.

Figure 8 is a perspective view of a sinusoidal wire connector apparatus of the present invention in a flattened configuration, prior to fabrication into its desired final configuration.

20 Figure 8a is a perspective view of the sinusoidal wire connector apparatus of Figure 8 following fabrication of into its desired final configuration, and showing the apparatus in a preferred implantation position forming a connection between adjacent tubular 25 anatomical conduits.

Figure 9 is a perspective view of a triplet coil 30 type connector apparatus of the present invention, showing the apparatus in a preferred implantation position forming a connection between adjacent tubular anatomical conduits.

Figure 10 is a longitudinal sectional view of a flanged tube connector of the present invention in a preferred implantation position forming a connection between adjacent tubular anatomical conduits.

35 Figure 10a is a perspective view of a segment of tubing which has been precut for fabrication into the flanged tubular connector apparatus of Figure 10.

-11-

Figure 10b is a side elevational view of the pre-notched segment of tubing shown in Figure 10a.

Figure 11a is a perspective view of a first embodiment of a flanged roll-up connector apparatus of 5 the present invention.

Figure 11b is a perspective view of a second embodiment of a flanged roll-up connector apparatus of the present invention.

Figure 11c is a perspective view of a flanged 10 cylindrical connector apparatus of the present invention.

Figure 12 is a perspective view showing the manner in which any of the connector apparatus of the present invention may be modified to form a non-perpendicular 15 connection between adjacent anatomical structures.

Figure 13 is a perspective view of a segment of myocardium showing an alternative application of the connector apparatus of the present invention to form a connection between a coronary blood vessel and a 20 chamber of the heart.

Figure 14a is a schematic showing of a retractable sheath type delivery catheter useable to deliver connector apparatus of the present invention.

Figure 14b is a schematic showing of an inflatable 25 balloon type delivery catheter useable to deliver connector apparatus of the present invention.

Figure 14c is a schematic showing of a push rod type delivery catheter useable to deliver connector apparatus of the present invention.

30 Figure 14d is a schematic showing of an alter-apposing slider sheath type delivery catheter useable to deliver connector apparatus of the present invention.

Figure 14e is a schematic showing of a rotatable 35 delivery catheter useable to deliver and implant connector apparatus of the present invention.

-12-

Figure 15a is a showing of a two-piece connector apparatus as described and claimed in parent application Serial No. 08/730,327, modified to illustrate the manner in which the connecting portion 5 of the connector apparatus may protrude through tissue and lay outside of the passageway which has been formed between the adjacent anatomical structures.

Figure 15a' is an exploded view of the connector apparatus shown in Figure 15a.

10

Detailed Description of the Preferred Embodiments

The following detailed description and the drawings to which it refers are provided for the purpose of describing and illustrating presently 15 preferred embodiments of the invention, and are not intended to limit the scope of the claims in any way.

It is to be understood that each of the structural elements attributes and components shown in the drawings for an embodiment may be incorporated into or 20 combined with any or all of the other embodiments of the invention, so long as such negation may be accomplished without negating the utility or functionality of that embodiment.

Furthermore, it is to be appreciated that no 25 effort has been made to exhaustively describe and illustrate each and every possible embodiment of the invention having each and every possible design or structure feature combineable therewith.

Specifically, the following elements, adaptations 30 or structural attributes may be incorporated into any or all of the embodiments described herein, irrespective of whether such elements, adaptations or attributes are specifically shown in any of the drawings.

35 1. Radio-opaque construction or radio-opaque markings to enable the connector to be

-13-

visualized by fluoroscopy, x-ray or Roentgenographic techniques;

2. Non-obstructive or minimally obstructive to flow of fluid through the openings in the anatomical structures between which the connection is formed;

3. Non-thrombogenic or antithrombogenic when used in blood-contacting applications and/or anti-infective or anti-microbial and/or radioactive so as to deter neointimal growth or natural closure or narrowing of the passageway.

4. Capable of withstanding the range of pressures which will be encountered in the intended anatomical application, such as pressures 140-180mmhg in applications wherein connections between arteries or an artery and vein are formed;

5. Capable of being operatively installed without causing significant necrosis or enhancing or inducing proliferation of tissue surrounding the connector apparatus;

6. Capable of expanding/contracting or otherwise adapting to compliance changes between the connected anatomical structures;

7. The portions of the connector apparatus which abut against or engage the luminal or inner wall of each anatomical structure may be shaped to conform to that luminal or inner wall (e.g., engagement members or flanges may be hemi-cylindrical bowed or cupped to conform to the wall of a blood vessel to which connection is made);

8. The connector apparatus may be structured or designed to maintain a desired cross-sectional dimension or diameter of the openings formed in the adjacent anatomical

-14-

structures and any interstitial passageway formed between such openings; and

9. The connector apparatus may preferably be formed of a continuous or single 5 structural element having minimal likelihood of breakage or dismemberment after implantation.

10. Capable of incorporating a flow control element or valve (e.g., a one-way check 10 valve) to control or maintain a specific pattern or type of flow (e.g., unidirectional flow) through the passageway.

11. The connection portion of the connector apparatus may be adapted to form passageways 15 of various shapes (e.g., cylindrical, ovoid, arcuate).

12. Capable of being removed after 20 implantation.

13. The connector apparatus may be constructed with varying amounts of 25 structural support or scaffolding, or may incorporate intraluminally placed structural or non-structural elements which will retard or restrain neointimal growth or natural closure or narrowing of the passageway.

14. The connector apparatus will preferably be capable of withstanding all forces (e.g., hemodynamic pressures, muscular contractions or other forces created by movement or impact 30 of the body) which will be encountered following implantation, without resultant adverse effect (e.g., breakage, dislodgement, slippage, movement or other untoward affect on the connector apparatus).

35. The connector apparatus may be constructed and configured so as to apply residual forces to compress or otherwise

-15-

minimize the length of the passageway between the first and second anatomical structures following implantation.

16. The connector apparatus may be adapted 5 to receive and transmit energy supplied through the delivery apparatus (e.g., delivery catheter). Such energy may serve to modify the surrounding tissue which defines the openings in the first and second 10 anatomical structures as well as any passageway created between interstitial tissue which resides between the anatomical structures.

17. The connector apparatus may be 15 configured to control or define the geometric shape of the passageway so as to maximize flow performance and/or to minimize adverse flow conditions such as turbulence.

18. The connector apparatus may be 20 constructed to support rotational twisting and torsion without adverse effects.

With reference to the drawings, Figure 1 provides a general showing of the manner in which the connector apparatus 10 of the present invention is implanted or 25 installed within openings formed in adjacent blood vessels BV₁, BV₂ to maintain side-by-side connection and direct alignment of the side wall openings formed in the blood vessel BV₁, BV₂. The blood vessels BV₁, BV₂ may be endogenous arteries and/or veins in their 30 natural anatomical positions, or may constitute one endogenous artery or vein having a synthetic or biological tube graft placed in juxtaposition thereto.

i. Coil Connectors

Figures 2-2''' show several variations of a first 35 embodiment 10a of the connector apparatus of the present invention. Each of the variants shown in Figures 2-2''' comprise a helical coil formed of

-16-

resilient or superelastic wire 12, such coil having opposite ends of a first diameter D_1 and a mid-portion of a second diameter D_2 . The second diameter D_2 of the mid-portion of the coil is smaller than the first

5 diameter D_1 of the ends, such that the apparatus 10a is generally of all hyperbolic or "hourglass" shape. However, it will be appreciated that other embodiments may also be provided, rather than the hyperbolic or hourglass shape shown in the drawings, the coil is of a

10 cylindrical or frusto-conical shape and is provided with additional engagement members which extend laterally outward from the opposite ends of the coil. The wire 12 of which the apparatus, 10a is formed is sufficiently resilient or superelastic in the range of

15 temperatures in which the apparatus 10a is used (i.e., at room temperature and body temperature) to allow the apparatus 10a to be initially radially compressed (and concurrently longitudinally elongated) into a relatively small diameter, compact configuration which

20 may be inserted into the lumen of a delivery catheter. The delivery catheter is then advanced through the desired anatomical passageway (e.g., blood vessel BV_1 , or BV_2 such that an opening of the catheter is located within the region between the side wall openings in the

25 adjacent anatomical conduits or blood vessels BV_1 , or BV_2 . Thereafter, the apparatus 10a is expelled out of the catheter and permitted to resiliently or elastically reassume its hyperbolic or hourglass configuration, such that the ends of the first diameter

30 D_1 will engage the walls of each anatomical conduit or blood vessels BV_1 , BV_2 and the mid-portion diameter D_2 will reside within the space or tissue tunnel created between the side wall of openings in the adjacent anatomical conduits or blood vessels BV_1 , BV_2 .

35 In the connector apparatus 10a shown in Figure 2, the entire apparatus 10a is formed of a tightly wound helical wire coil such that each adjacent convolution

-17-

of the wire 12 is in close juxtaposition or abutment to the adjacent convolution thereof. This provides a hyperbolic coil of substantially continuous construction, as shown in Figure 2.

5 Figure 2' shows a variant of the first embodiment of the connector apparatus 10a wherein the resilient or superelastic wire 12 is tightly wound at either end such that multiple adjacent convolutions of the wire are closely spaced or in direct abutment at either end 10 of the apparatus 10a', while the mid-portion of the apparatus D₂ comprises a more loosely wound traversing segment 14 comprising a single strand of the wire 12 which extends from the abutting convolutions at one end 15 of the apparatus 10a' to the abutting convolutions at the other end of the apparatus 10a'.

In the variant shown in Figure 2'', the apparatus 10a'' comprises tightly wound helical wire coil segments of generally spiral or frusto-conical configuration located at either end, with a tubular 20 sleeve 16 forming the mid portion of the apparatus 10a''. This tubular sleeve 16 may be formed of tubular plastic material such as polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (EPTFE) 25 polyethylene (PE), silicone, polyurethane (PU), or polyester. Alternatively, the tubular sleeve 16 may be formed of natural, autologous or xenograft material. The spiral or frusto-conical wire coil segments located 30 at either end of the apparatus 10a'' may comprise the opposite ends of a continuous wire coil which extends through the lumen of the tubular sleeve 16, or may comprise two separate, non-continuous coil segments each of which is affixed or mounted to one end of the tubular sleeve 16.

The variant of the connector apparatus 10a''' 35 shown in Figure 2''' comprises a continuous, tightly wound helical coil of resilient or superelastic wire 12 which is similar in configuration to that shown in

-18-

Figure 2, but wherein two or more adjacent convolutions of the wire 12 at the mid-portion of the apparatus 10a'' have been welded, adhered or otherwise fused to one another to form a continuous, tubular mid-portion 5 of diameter D_2 . Such fusion of the adjacent convolutions of wire 12 forming the mid-portion of the apparatus 10a'' may comprise weldments 18, or adhesive or any other suitable fusion material capable of welding adhering or otherwise fusing the adjacent 10 convolutions of wire 12 to one another.

It will be appreciated that many of the embodiments of the connector apparatus 10 of the present invention may be constructed so as to be biased to a longitudinally shortened or longitudinally collapsed configuration so as to longitudinally compress or confine the tissue between the first and second openings formed in the first and second anatomical structures or blood vessels BV_1 , BV_2 . Figure 2'''' shows an example of this concept, as applied to 15 the helical coil connector of Figure 2. As shown in Figure 2''''', the helical coil connector 10a''', when in its relaxed state, has a longitudinally compact configuration wherein the first and second ends of the coil are close-spaced. When this embodiment of the 20 connector apparatus 10a'''' is implanted within the first and second openings formed in the first and second anatomical structures or blood vessels BV_1 , BV_2 , the opposite ends of the connector apparatus 10a'''' will engage the openings in the adjacent anatomical 25 structures or blood vessels BV_1 , BV_2 and will conform to the length of the channel formed therebetween. In this manner, the resilient nature of the coil will tend 30 to urge or pull the opposite ends of the coil inwardly, thereby longitudinally compressing or constraining the tissues which are located between the opposite ends of 35 the coil. It should be noted, however, that the force exerted by the coil is preferably not to great as to

-19-

cause undesirable tissue necrosis or undesirable proliferation of tissues which are longitudinally compressed or constrained by this embodiment of the apparatus 10a''). It will be further appreciated that 5 the biasing of the connector apparatus 10a'') to such longitudinally compact configuration will enable the connector apparatus 10a'') to be used in channels or passageways of varying length, thereby eliminating the need for providing manufacturing and stocking a variety 10 of such connector apparatus 10a'') having differing lengths.

ii. Mesh Connectors

Figures 3-3'') show several variants of tubular mesh connector apparatus 10b having inwardly arched (e.g., hyperboloidal side walls.) 15

Figure 3 shows a basic hyperbolic mesh connector apparatus 10b which comprises a tube formed of wire mesh having an inwardly arched, hyperboloidal or "hourglass" configuration. However, it will be 20 appreciated that the wire mesh connectors may alternatively be of cylindrical or frusto-conical configuration with additional engagement members or projections extending laterally outward from the opposite ends of such cylindrical or frusto-conical 25 mesh tube. This embodiment of the connector apparatus 10b has distal ends of a first diameter D_1 , and a second diameter D_2 . The diameter D_2 of the mid-portion is smaller than the diameters D_1 of the ends, thereby providing the desired hyperbolic or hourglass 30 configuration. The mesh structure of the apparatus 10b is preferably formed of a multiplicity of wire segments 18 which are interwoven into the desired mesh structure. The wire segments 18 may be formed of a resilient or superelastic wire material so as to render 35 the apparatus 10b radially compressible (and concurably longitudinally elongatable) to a reduced diameter capable of being positioned within a delivery catheter,

-20-

and to subsequently allow the apparatus 10b to resiliently self-expand to its desired hyperbolic or hourglass configuration of diameters D_1 and D_2 after having been expelled from the constraining catheter or 5 other delivery device. In some applications, the hyperbolic or hourglass configuration of the apparatus 10b will be such that the end portions of diameter D_1 will engage the walls of the adjacent anatomical passageways or blood vessels BV_1 , BV_2 , so as to hold 10 the apparatus 10b in the desired position between the anatomical passageways or blood vessels BV_1 , BV_2 . In other embodiments, as shown in Figures 3', 3'', and 3''', one or more splayable engagement members 20 may be formed on one or both ends of the wire mesh tube to 15 facilitate engagement of the opposite ends of the apparatus 10b to the walls of the connected anatomical passageways or blood vessels BV_1 , BV_2 .

Figure 3' shows a variant of the apparatus 10b' having wire loop type engagement members 20 formed on 20 both ends thereof. Initially, as shown in Figure 3', the wire loop type engagement members 20 will be deployed in extended positions such that they extend longitudinally from either end of the wire mesh tube and are parallel or close to parallel to the 25 longitudinal axis LA of the apparatus 10b'. These engagement members 20 may be formed of resilient or spring material so as to be self-splaying (Fig. 3'') or may be formed of bendable or malleable material so as to be pressure-splayable (Fig. 3''').

30 With reference to the particular variant Figure 3'', the resilient or self-splayable engagement members 20 will, when released from the surrounding constraint of the delivery catheter, self-splay (i.e., curve outwardly) to their desired engagement positions 35 wherein such engagement members 20 may be generally perpendicular or near perpendicular to the longitudinal axis LA of the device 10b''.

-21-

With reference to Figure 3''', in embodiments wherein the engagement members 20 are formed of plastically deformable or malleable metal or other material which is pressure-deformable, the apparatus 5 10b''' will be initially positioned within the adjacent openings formed in the first and second anatomical passageways or blood vessels BV₁, BV₂ such that the engagement members 20 formed on one end of the apparatus 10b''' protrude or extend into the lumen of 10 the first anatomical passageway or blood vessel BV₁, and the engagement members 20 on the opposite end of the apparatus 10b''' protrude or extend into the lumen of the second anatomical passageway or blood vessel BV₂. A pressure exerting apparatus, such as the dual balloon 15 catheter 24 shown in Figure 3''', is then utilized to exert, pressure against the engagement members 20 to cause the engagement members to splay or deform outwardly to positions which are substantially perpendicular or near perpendicular to the longitudinal 20 axis LA of the apparatus 10b''', or such that the engagement members will embed or hook into the adjacent tissue of the anatomical structure. In this manner, the engagement members 20 may abut against or enter the adjacent walls of the first and second passageways or 25 blood vessels BV₁, or BV₂. One type of dual balloon catheter 24 useable for this purpose comprises an elongate pliable catheter 26 having a singular dumbbell-shaped or hour glass shaped balloon or the combination of a first balloon 28 and a second balloon 30 formed at spaced apart location thereon, as shown. The first balloon 28 and second balloon 30 are spaced apart or separated by a distance which is equal to, or bears a predetermined relationship to, the length of the apparatus 10b''' such that the first balloon 28 may 30 35 be positioned within and adjacent the longitudinally extended engagement members 20 on one end of the apparatus 10b''' and the second balloon 30 may be

-22-

positioned within and adjacent the longitudinally extended engagement members 20 on the other end of the apparatus 10b'''. Thereafter, the first and second balloons 28, 30 are inflated causing them to exert 5 pressure against the engagement members 20 on both ends of the apparatus 10b''', resulting in the desired splaying or bending of the engagement members 20 to their engagement positions wherein they are generally in apposition to, or embedded in, the wall(s) of the 10 anatomical structure on either side of the channel. Thereafter, the first balloon 28 and second balloon 30 are deflated and the catheter 26 is removed, leaving the connector apparatus 10b''' in its installed and implanted location between the first and second 15 passageways or blood vessels BV₁, BV₂.

iii. Tube Connectors

Figure 4-4''' show several variants of a tube connector apparatus 10c 10c''' which generally comprises a segment of radially compressible or 20 collapsible resilient tube member 30 having inwardly arched, hyperboloidal or "hourglass" shaped side walls having opposite ends of a first diameter D₁ and a mid-portion of a second diameter D₂. It will be appreciated, however, that the tube may alternatively 25 be of cylindrical or frusto-conical shape with additional engagement members which extend laterally outward from either end of the tube, which may not require expansion for placement.

Specifically, Figure 4 shows a connector apparatus 30 10c which comprises a hyperbolic or hourglass shaped tube member 36 which is positionable within side openings formed in two adjacent anatomical passageways (e.g., blood vessels BV₁, BV₂) such that one end of the tube member 36 having diameter D₁ will engage the 35 luminal surface of the one of passageways or blood vessels BV₁, and the other end of the tube member 36 also of diameter D₁ will engage the luminal surface of

-23-

the other passageway or blood vessel BV_2 . The outwardly tapered or enlarged diameters of the ends of the tube members 36 thus serve to engage the anatomical passageways or blood vessels BV_1 , BV_2 without the need 5 for additional flanges, projections or other engagement members on either end of the tube member 36.

Figure 4' shows the hyperbolic tube member 36 of Figure 4 with optional engagement members 20 formed on both ends thereof. These engagement members 20 may 10 comprise flanges, tabs, or, as shown, splayable wire loops. These engagement members 20 are initially disposed such that they extend longitudinally from either end of the hyperbolic tube member 36 and are parallel or close to parallel to the longitudinal axis 15 LA of the tube member 36. After the tube member 36 has been placed in its desired position between the two anatomical passageways or blood vessels BV_1 , BV_2 , the engagement members 20 are caused to splay outwardly such that they become perpendicular or close to 20 perpendicular to the longitudinal axis LA of the tube member 36, as shown in Figures 4'' and 4'''. The engagement members 20 may be formed of resilient, superelastic, shape memory or spring material so as to be self-splayable (Fig. 4'') or may be formed of 25 bendable or plastically deformable material so as to be pressure-splayable (Fig. 4''').

With reference to Figure 4'', a self-splayable embodiment of the apparatus 10c comprises engagement members 20 which, when relieved of the surrounding 30 constraint of a delivery catheter or other delivery apparatus, will self-splay to their outwardly deployed positions wherein they are generally perpendicular or close to perpendicular to the longitudinal axis LA of the apparatus 10c''.

35 With reference to Figure 4''', there is shown an embodiment of the apparatus 10c''' wherein the engagement members 20 are pressure-splayable. This

-24-

embodiment of the apparatus 10c''' is initially positioned such that the engagement members 20 on one end of the apparatus 10c''' extend into the lumen of one anatomical passageway or blood vessel BV₁, and the 5 engagement members 20 on the other end of the apparatus 10c''' extend into the lumen of the second anatomical passageway or blood vessel BV₂. A pressure exerting apparatus, such as the above-described balloon catheter 26 having first and second balloons 28, 30, is then 10 utilized to exert pressure upon the engagement members 20 to cause the engagement members to move from their longitudinally extended positions (Fig. 4') to their outwardly splayed (i.e., operative positions wherein they are generally perpendicular or close to 15 perpendicular to the longitudinal axis LA of the apparatus 10c'''. Thereafter, the balloons 28, 30 of the balloon catheter 26 or other pressure-exerting elements of any suitable pressure-exerting tool are deflated or otherwise disengaged and the catheter 26 is 20 removed, thereby leaving the apparatus 10c in its desired position between the first and second anatomical passageways or blood vessels BV₁, BV₂, with the engagement members 20 in direct abutment with the lumen surfaces of the respective first and second 25 passageways or blood vessels BV₁, BV₂.

iv. Cylindrical Connectors with Engagement Surface

Figures 5-5'' show several variants of a cylindrical connector apparatus 10b of the present 30 invention. This cylindrical connector apparatus 10b generally comprises a cylindrical, tubular mid-portion 38 of substantially constant diameter, in combination with one or more engagement members 20 formed on either end thereof. The engagement members 20 may comprise 35 splayable wire loops as shown in the drawings, or any other suitable type of flange, lip, tab or other member capable of abutting against the luminal wall of an

-25-

anatomical passageway or blood vessel BV_1 , BV_2 to prevent longitudinal slippage or movement of the tubular mid-portion in at least one direction. In this manner, the formation and deployment of such engagement member on either end of the tubular mid-portion 38 will anchor and hold the tubular mid-portion 38 in its desired implantation position between the openings formed in the adjacent passageways of blood vessels BV_1 and BV_2 .

10 The tubular mid-portion 38 of the apparatus 10d may comprise a tube of resilient plastic, woven dacron or any other suitable material which is collapsible to a small diameter so as to be initially packed within the lumen of a delivery catheter, and which is

15 subsequently radially expandable or unfoldable to a desired diameter D such that blood or other bodily fluid may flow through the cylindrical tubular member 38 from one anatomical passageway or blood vessel BV_1 into another anatomical passageway or blood vessel BV_2 .

20 Alternatively, it will be appreciated that the tubular mid-portion 38 may be a rigid or semi-rigid tube formed of metal, carbon or alloy which is generally not radially expandable, but which is provided with

25 additional engagement members which may be splayed or extended from opposite ends of the tubular mid-portion 38 to engage or embed within the adjacent tissue of the anatomical structure. These rigid or semi-rigid tubular mid-portions 38 may be of any suitable shaped configuration, including cylindrical, frusto-conical or

30 hyperbolic (e.g., hourglass) shape.

The engagement members 20 are preferably initially disposed in positions wherein they are longitudinally extended from either end of the cylindrical tubular mid-portion 38 generally parallel or close to parallel to the longitudinal axis LA of the apparatus 10d as shown in Figure 5. The engagement members 20 may be formed of resilient, superelastic, shape memory or

-26-

spring material so as to be self-splayable (Fig. 5) or may be formed of bendable or plastically deformable material so as to be pressure-splayable (Fig. 5'')

With reference to Figure 5', a self-splayable 5 embodiment of apparatus 10d comprises engagement members 20 which, when relieved of the surrounding constraint of the delivery catheter or other delivery apparatus, will self-splay to their outwardly deployed position wherein they are generally perpendicular or 10 close to perpendicular to the longitudinal axis LA of the apparatus 10b'.

With reference to Figure 5'', in embodiments of the apparatus 10b'' wherein the engagement members 20 are pressure-splayable. This embodiment of the 15 apparatus 10b'' is initially positioned such that the engagement members 20 on one end of the apparatus 10b'' extend into the lumen of one anatomical passageway or blood vessel BV₁, and the engagement members 20 on the other end of the apparatus 10b'' extend into the lumen 20 of the second anatomical passageway or blood vessel BV₂. A pressure exerting apparatus, such as the above-described balloon catheter 26 having first and second balloons 28, 30, is then utilized to exert pressure upon the engagement members 20 to cause the engagement 25 members to move from their longitudinally extended positions (Fig. 5) to their outwardly splayed (i.e., operative) positions wherein they are generally perpendicular or close to perpendicular to the longitudinal axis LA of the apparatus 10d'' (Fig. 5''). 30 Thereafter, the balloons 28, 30 of the balloon catheter 26 or other pressure-exerting elements of any suitable pressure-exerting tool are deflated or otherwise disengaged and the catheter 26 is removed, thereby leaving the apparatus 10d'' in its desired position 35 between the first and second anatomical passageways or blood vessels BV₁, BV₂ with the engagement members 20

-27-

in direct abutment with the respective first and second passageways or blood vessels BV₁, BV₂.

v. Rivet Type Connector Apparatus

Figure 6-6'' show several variants of rivet type connector apparatus which comprise a first tubular member 40 having a first engagement flange 44 formed thereon and a second tubular member 42 having a second engagement flange 46 formed thereon. The first and second tubular members 40, 42 are connectible to one another such the lumens of the tubular members 40, 42 are in direct alignment thereby forming a singular lumen 41 through the center of the apparatus 10e, 10e', 10e''.

Various snap-fitting or frictional engagement systems may be utilized to securely connect the first and second tubular members 40, 42 to one another, and examples of such snap-fitting or frictional engagement systems are shown in the showings of Figures 6, 6' and 6''.

With specific reference to Figure 6, there is provided an annular groove 48 in the outer surface of the first tubular member 40 and a corresponding raised ridge 50 in the outer surface of the second tubular member 42. The raised ridge 50 is sized and configured to snap fit and seat within the groove 48 as the first tubular member 40 is advanced into the interior of the second tubular member 42. When the annular ridge 50 is seated within the corresponding groove 48, the respective engagement flanges 44, 46 will be held in fixed spaced-apart relation to one another such that the distance between flanges 44, 46 will result in engagement of the flanges with the respective luminal walls of the anatomical passageways or blood vessels BV₁, BV₂ which are intended to be connected by the apparatus 10e.

Figure 6' shows another connector apparatus 10e comprising a first tubular member 40' and a second

-28-

tubular member 42'. Engagement flanges 44', 46' are formed about the outer ends of the first and second tubular members 40', 42', respectively. When the non-flanged end of the first tubular member 40' is advanced 5 into the non-flanged end of the second tubular member 42', the respective lumens of the two tubular members 40', 42' will be in direct alignment so as to form a single continuous lumen 41 through the center of the apparatus 10e'. The outer surface of the first tubular 10 member 40 is tapered inwardly toward the non-flanged end such that, as it is advanced into the interior of the second tubular member 42' the outer surface of the first tubular member 40' will tighten against and frictionally engage the inner surface of the second 15 tubular member 42', thereby holding the first and second tubular members 40', 42' in fixed, connected relation to one another such that the engagement flanges, 44', 46' are held in spaced-apart relation such that the distance therebetween will cause the 20 flanges 44', 46' to be in abutting contact with the respective luminal surfaces of the first and second passageways or blood vessels BV₁, BV₂.

vi. Elastomeric Connector Apparatus

Figures 7a-7d' show examples of connector 25 apparatus 10h, 10i of the present invention formed of elastomeric materials such as a resilient elastomeric polymer (e.g., polyurethane, silicone, etc.).

In particular, Figures 7a, 7a' show an embodiment 30 of a connector apparatus 10h comprising an elastomeric, cylindrical tube 60 having a hollow lumen 62 extending longitudinally therethrough and four engagement members in the nature of tabs formed on opposite ends of the tube 60 and extending outwardly therefrom in directions which are substantially perpendicular to the 35 longitudinal axis LA of the tube 60.

Figures 7b, 7b' show another embodiment of a connector apparatus 10i which comprises an ovoid tube

-29-

member 70 formed of elastomeric material and substantially rectangular engagement members 74 in the nature of flanges formed on either end thereof. The engagement members 74 extend in directions which are 5 parallel to the length-wise axis of the ovoid lumen 72 of the ovoid tube member 70, as shown. The provision of the ovoid tube member 70 having the ovoid lumen 72, and the corresponding configuration and directional orientation of the engagement members 74 will enable 10 this embodiment of the connector apparatus 10i to be utilized in blood vessels or anatomical passageways of relatively small diameter, with openings which are elongate or ovoid so as to permit a greater amount of body fluid to flow through the openings than would be 15 possible than if the openings were of a circular configuration. This is due to the fact that the maximum diameter of any circular opening formed in the side wall of a passageway or blood vessel BV₁, BV₂ cannot exceed the diameter of the passageway or blood 20 vessel BV₁, BV₂, while elongate or ovoid openings may have a width which is equal to or slightly less than the diameter of the passageway or blood vessel BV₁, BV₂ and a length which is larger than the diameter of such 25 passageway or blood vessel BV₁, BV₂. This tube member 70 may also incorporate any suitable reinforcing material, such as wire. This ovoid or non-circular configuration of the tube member 70 and its lumen 72 may be incorporated into any of the embodiments of the invention described herein, and is not necessarily 30 limited to the particular elastomeric embodiment shown in Figures 7b, 7b'.

In each of these elastomeric embodiments shown in Figures 7a, 7a', 7b, 7b', the material of which the apparatus 10h, 10i is formed is sufficiently resilient 35 and compressible to be initially packed into the lumen of a delivery catheter, and is sufficiently resilient such that when the apparatus 10h, 10i is expelled or

-30-

otherwise passed out of the delivery catheter, the absence of restraint upon the apparatus 10h, 10i will allow the apparatus to assume its fully expanded and operative configuration as shown in the figures. When 5 in such fully expanded and operative configuration, the abutment members 64 or 74 will abut against the luminal surfaces of the passageways or blood vessels BV₁, BV₂, in the regions immediately surrounding the openings formed therein, and the tube members 60, 70 of the 10 apparatus 10h, 10i will extend between the respective passageways or blood vessels BV₁, BV₂, thereby forming a conduit or passageway between the openings formed in the passageways or blood vessels BV₁, BV₂.

15 vii. Wire Connector Apparatus with Optional
 Covering

Figure 7c-7d' show examples of wire connector members with optional coverings formed thereon. These coverings may cover all or any portion of the apparatus. For example, such covering may be formed on 20 the connecting portion or mid-portion of the apparatus so as to form a sleeve or covering which lines the passageway, while the engagement portions (e.g., extendable engagement members) of the apparatus may remain devoid of such covering. Such coverings may be 25 formed of any suitable material including, but not limited to, elastomeric material, fabrics (e.g., woven polyester) or natural materials such as autologus or xenograft material.

With specific reference to the embodiment shown in 30 Figure 7c, there are provided two separate generally U-shaped wire members 80 which are partially embedded with an elastomeric tube member 82 having a hollow lumen 84 extending longitudinally therethrough. Optionally, the portions of the wire members 80 which 35 protrude out of the elastomeric tube member 82 may also be covered with elastomeric material 86. In this manner, the portions of the wire members 80 (with or

-31-

without elastomeric covering 86) which protrude outwardly from the elastomeric tube member 82 may serve to abut against and engage the luminal surfaces of the passageways or blood vessels BV₁, BV₂, immediately 5 adjacent the side wall openings formed therein, while the elastomeric tube member 82 will form a traversing conduit between the passageways or blood vessels BV₁, BV₂. In this manner, the protruding portions of the wire members 80 with or without their elastomeric 10 coverings 86 will serve to anchor and hold the apparatus 10j in its desired position between the passageways or blood vessels BV₁, BV₂, such that body fluid may pass through the lumen 84 of the tube member 82, from one of the passageway or blood vessel BV₁, to 15 the other passageway or blood vessel BV₂.

Figure 7d-7d' shows another embodiment of a connector apparatus 10k which comprises a continuous segment of wire which is formed into a configuration having four generally U-shaped projections 92 extending 20 laterally outward therefrom in opposite directions.

This apparatus 10k may be utilized as a connector apparatus in and of itself, without any elastomeric covering, such that the U-shaped projection 92 may be placed in abutment with the luminal surfaces of the 25 adjacent passageways or blood vessels BV₁, BV₂, thereby clipping or holding the openings formed in the passageways or blood vessels BV₁, BV₂ in alignment with one another, and establishing the desired 30 interconnection of the passageways or blood vessels BV₁, BV₂.

Figure 7d' shows an optional elastomeric tube member 94 having the central portion of the wire member formed therein such that the U-shaped projections 92 extend laterally outboard and away from the elastomeric 35 tube member 94. In this manner, the elastomeric tube member is provided with a hollow lumen 96 extending longitudinally therefrom and, when the U-shaped

-32-

projections 92 are in abutment with the lumenal surfaces of the passageways or blood vessels BV₁, BV₂, the elastomeric tube member 94 will form a discrete conduit or passageway whereby body fluid may pass

5 through the lumen 96 of the tube member 94 from one passageway or blood vessel BV₁, to the other passageway or blood vessel BV₂. Optionally, the elastomeric material may also extend over and cover the U-shaped projections 92, as denoted by the dotted lines in

10 Figure 7b'.

viii. Sinusoidal Wire Connector Apparatus

Figures 8-8a show a connector apparatus 101 which is formed of a wire member 100 which has been formed or bent into multiple sinusoidal waves or convolutions, some of such sinusoidal waves or convolutions being of a first size 102 and others of such sinusoidal waves or convolutions being of a second size 104. Preferably the smaller sinusoidal waves or convolutions 102 are formed in pairs or couplets, with the larger sinusoidal waves or convolutions 104 being also formed in pairs or couplets which are positioned alternately with the pairs or couplets of the smaller sinusoidal waves or convolutions 102. In this manner, when the opposite ends of the wire member 100 are fused or coupled together by way of a sleeve member 101, the smaller sinusoidal waves or convolutions 102 will define a hollow passageway 106 and the larger sinusoidal waves or convolutions 104 may be bent laterally outward from the center of the passageway 106 so as to abut against and engage the respective lumenal surfaces of the anatomical passageways or blood vessels BV₁, BV₂, as shown in Figure 8a. In this manner, the sinusoidal wire connector apparatus 101 shown in Figures 8, 8a serves to hold the first and second blood vessels BV₁, BV₂ in connection with one another such that side wall openings formed in such first and second blood vessels BV₁, BV₂ will be maintained in direct alignment with

-33-

one another, thereby allowing body fluid to pass through the passageway 106 of the connector apparatus 101 from the lumen of one blood vessel BV₁ to the lumen of the other blood vessel BV₂.

5 It will be appreciated that a covering formed of any suitable material (e.g., elastomeric, fabric, natural graft material, etc.) may be formed on all or part of the device. for example, a tubular covering may be mounted on the mid-portion formed by the smaller 10 sinusoidal waves or convolutions 102 and the basal portions of the larger sinusoidal waves or convolutions 104, and such cover may optionally may extend outwardly over the entireties of the laterally bent portions of the larger sinusoidal waves or convolutions 104, in 15 accordance with the invention as described hereabove in relation to Figures 7c and 7d'.

ix. Triplet Coil Type Connector Apparatus

Figure 9 shows a triplet coil type connector apparatus 10m of the present invention comprising a 20 first coil portion 114a, a second coil portion 114b and a third coil portion 114c. The apparatus 10m is formed of a continuous wire member 110 which has been helically wound to form a coil wherein adjacent convolutions of the coil are in direct abutment with 25 one another, or are closely spaced to one another.

The first coil segment 114a has a first longitudinal axis LA₁. The coil segment 114b has a second longitudinal axis LA₂ which may be perpendicular to the first longitudinal axis LA₁ of the first coil 30 segment 114a. The third coil segment 114c has a third longitudinal axis LA₃ which may be parallel to the first longitudinal axis LA₁ of the first coil segment 114a and perpendicular to the second longitudinal axis LA₂ of the first coil segment 114b.

35 The length l of the second coil segment 114b may vary depending upon the desired distance between the first and second passageways or blood vessels BV₁, BV₂.

-34-

The wire member 110 may be formed of any suitable material such as stainless steel, superelastic nickel titanium alloy, etc. The apparatus 10m is preferably sufficiently pliable and resilient such that the three 5 coil segments 114a, 114b, 114c may be disposed in direct alignment with one another about a common longitudinal axis and radially compressed (and concurrently elongated) so as to be positionable within the lumen of a delivery catheter. For most 10 intravascular applications, it will be desirable to compress the entire apparatus 10m to a compact configuration which may be mounted within or upon a delivery catheter of the type referred to in more detail herebelow. Thereafter, the delivery catheter 15 may be advanced through the second blood vessel BV₂, through the opening formed between the second blood vessel BV₂ and first blood vessel BV₁, and into the lumen of the first blood vessel BV₁. Thereafter, the third coil segment 114c will be expelled out of the 20 delivery catheter and allowed to assume its radially expanded, operative configuration as shown in Figure 9.

Thereafter, the delivery catheter will be retracted to a position within or adjacent the opening between the first blood vessel BV₁ and second blood 25 vessel BV₂, and the second coil segment 114b will be expelled or advanced out of the delivery catheter and allowed to radially expand to its expanded, operative configuration and attitude about the second longitudinal axis LA₂ as shown in Figure 9. 30 Thereafter, the delivery catheter is further retracted into the lumen of the second blood vessel BV₂ and the first coil segment 114a is expelled or advanced out of the delivery catheter and allowed to expand to its expanded, operative configuration as shown in Figure 9. 35 In this manner, the first and third coil segments 114a, 114c will seat against and frictionally engage the luminal surfaces of the first and second blood

-35-

vessels BV_1 and BV_2 , respectively, and the second coil segment 114b will traverse any space which exists between the first and second blood vessels BV_1 and BV_2 . It will be appreciated, that a tubular covering or 5 enclosure may be formed upon the inner and/or outer surfaces of any and/or all of the coil members 114a, 114b, 114c to provide a flow conduit which is impermeable to fluid, or to enhance the biocompatibility of the apparatus 10m.

10 **x. Flanged Tube Type Connector Apparatus**

Figures 10-10b show a flanged tube type connector apparatus 10n of the present invention. It will be appreciated that, in addition to the specific flang configurations shown in the drawings, such flanges may 15 be formed in many different configurations and designs and/or may include notches, geometries and configurational attributes designed to enhance the ability of the connector apparatus to withstand longitudinal contractions/expansions and 20 rotational/orientation motions of the surrounding tissue.

The embodiment 10n shown in Figure 10, comprises a segment of tubing which has been notched and formed such that semi-cylindrical or arcuate flanges 120 25 extend laterally outward from opposite sides of either end of a cylindrical or tubular mid-portion 122. When implanted between two blood vessels, as illustrated in Figure 10, the semi-cylindrical or arcuate flanges 120 will abut against the luminal surfaces of the blood 30 vessels and will approximate the semi-cylindrical or arcuate shape of the adjacent luminal blood vessel surface. The tubular or cylindrical mid-portion 22 forms a discrete tubular conduit which extends between the openings formed in the adjacent blood vessels, 35 thereby providing a substantially fluid tight conduit through which blood or other bodily fluid may pass.

-36-

Figures 10-10b illustrate a preferred method of manufacturing this flanged tube type connector apparatus 10n. With reference to Figure 10a, a segment of cylindrical tubing formed of resilient metal, 5 resilient plastic, shape memory alloy or other suitable material is precut such that two (2) longitudinal notches 124 (e.g., rectangular notches) are formed in each end of the tube, at locations directly opposite one another, as shown. Thereafter, two transverse 10 notches 126 (e.g., arcuate or wedge shaped notches) are formed on either side of the tube such that the center of each such transverse notch 126 is approximately 90° from the centers of the adjacent longitudinal notches 124 formed on that end of the tube. Thereafter, the 15 protruding end portions of the notched tube are deformed or bent outwardly, as indicated by the arrows on Figure 10a. This results in the formation of the connector apparatus 10n shown in Figure 10 comprising the tubular mid-portion 122 having the arcuate or semi- 20 cylindrical flanges 120 which extend laterally outward from each end of the tubular mid-portion 122.

xi. Cylindrical Connectors Having Ribbed Outer Surfaces

Figures 11a-11c show three embodiments of 25 externally ribbed cylindrical connectors 10o, 10p, 10q of the present invention.

The connector 10o shown in Figure 11a comprises a cylindrical or tubular body 130 formed of a rolled sheet of resilient metal or plastic having overlapping 30 ends 132 such that the rolled cylindrical body may be radially compressed to a radially compact diameter, and will subsequently resiliently return to a radially expanded diameter as shown in Figure 11a. Cylindrical flanges or ribs 134 are formed about either end of the 35 rolled tube 130, as shown. In this manner, the apparatus 10o may be held in its radially compact state within an introducer or catheter and delivered into a

passageway formed between two anatomical structures, where it is allowed to radially expand to its operative configuration. Such radial expansion will cause the flange 134 at one end of the rolled cylindrical body 130 to abut against and engage the luminal surface of a first blood vessel or anatomical structure, surrounding a first opening formed in that blood vessel or anatomical structure. Similarly, the flange or rib 134b at the opposite end of the rolled tubular body 130 will abut against and engage the luminal surface surrounding an opening formed in a second blood vessel or other anatomical structure.

Figure 11b shows another ribbed connector apparatus 10p which also comprises a rolled cylindrical body portion 136 formed and configured the same as that shown in Figure 11a. In this apparatus 10p, a plurality of annular flanges or ribs 138 are formed about the outer surface of the rolled cylindrical body 136. When this apparatus 10p is delivered into a passageway between two blood vessels or other anatomical structures and allowed to expand, the flanges or ribs 138 on the outer surface of the rolled cylindrical body will embed into or engage interstitial tissue which surrounds the cylindrical body 136, thereby holding the apparatus 10p in its desired position between openings formed in adjacent blood vessels or anatomical structures. It will be appreciated that this embodiment of the apparatus 10p will be particularly useful in applications wherein firm interstitial tissue surrounds the passageway which extends between the openings formed in the adjacent blood vessels or anatomical structures. Indeed, this apparatus 10p is devoid of any flanges projections or surfaces which will abut against or engage the luminal surfaces of the adjacent blood vessels or anatomical structures, and relies instead on the engagement of the ribs or flanges 138 with the interstitial tissue to

-38-

prevent the apparatus 10p from dislodging or longitudinally moving following implantation.

Figure 11c shows another example of a ribbed cylindrical connector apparatus 10g comprising a 5 continuous cylindrical tubular body 140 having a helical rib or flange 142 formed about the outer surface thereof. The continuous cylindrical body 140 differs from the rolled cylindrical bodies of the embodiments 10o, 10p shown in Figures 11a and 11b in 10 that it does not have overlapping ends and can not be radially compressed in a "roll-up" state. Rather, the cylindrical body 140 of this apparatus 10g is of a continuous cylindrical structure and is formed of resilient or collapsible material that will enable the 15 apparatus 10g to be placed in a radially compact or reduced state for delivery into a passageway formed between openings and adjacent blood vessels or anatomical structures. After the tubular body 140 has been delivered and expanded to its operative 20 configuration as shown in Figure 11c, the helical outer rib or flange 142 will engage the interstitial tissue surrounding the passageway. As in the embodiment shown in Figure 11b, this apparatus 10g will be particularly useable in applications wherein the passageway formed 25 between the blood vessels or other anatomical structures has firm surrounding interstitial tissue into which the helical rib or flange 142 may imbed.

30 xii. Possible Modifications Of Embodiments To Accommodate Diagonal Passageways or Connections Between Anatomical Structures Other Than Blood Vessels

35 Figures 12 and 13 are intended to show modifications and alternative applications which may be applicable to all of the connector apparatus show in Figures 1-11.

Figure 12 is illustrative of the concept of forming the ends of each connector apparatus 10 such

-39-

that the ends are non-perpendicular to the longitudinal axis LA of the apparatus 10. Such angle-cutting of the ends of the connector apparatus 10 will be applicable when the connector apparatus 10 is to be disposed 5 within a diagonal or curved passway formed between openings which are not directly opposite one another on adjacent anatomical structures or blood vessels BV₁, BV₂. This aspect of the invention will be particular applicable in certain arterial bypass procedures, such 10 as those described in United States Patent Applications Serial Nos. 08/730,327 and 08/730,496, when it is desired to form curved or diagonal blood flow passageways to minimize turbulence and to promote substantially laminar blood flow through the passageway 15 and into the bypass vessel.

Figure 13 shows a connector apparatus 10, which has the configuration of the specific apparatus 10k shown in Figure 7d, disposed within a transmyocardial passageway formed between a coronary blood vessel CBV 20 and the left ventricle LV of the heart. In this manner, Figure 13 serves as an example of an application wherein any or all of the connector apparatus 10 of the present invention may be used to form a connection between anatomical structures other 25 than two blood vessels (i.e., a coronary blood vessel and a chamber of the heart).

xiii. Possible Modification of Embodiments to Accommodate or Conform to Passageways of Differing Length

30 It will be appreciated by those skilled in the art that the length or distance between the first and second anatomical structures may vary considerably. Thus, for embodiments of the connector apparatus 10 which are of fixed length, it may be desirable to 35 manufacture or provide such connector apparatus in a variety of lengths and sizes so as to allow the operator to select the appropriate length or size for

-40-

use in the instant application. Alternatively, many if not all of the embodiments of the present invention may be constructed such that the connecting portion of the connector apparatus 10 is elastic, adjustable, telescoping, distendable, of according configuration, or otherwise adjustable to accommodate or conform to passageways of differing length.

5 5. **xiv. Delivery and Implantation of the Connector Apparatus**

10 10. It should be generally understood that the connector may be delivered via any number or possible delivery mechanisms including but not limited to:

1. 11. Delivery mechanisms which trap the connector initially within an inner tubular member and an outer tubular member wherein movement of the one member relative to the other allows the connector to be exposed and deployed at first partially to allow the first set of engagement members to come in contact with the first lumen and then deployed fully to allow the second set of engagement members to come into contact with the second lumen.
2. 16. Connectors which are mounted onto a balloon, covered or non-covered by a temporary sheath, and then deployed with the assistance or forcibly directed by the balloon to their engaging position.
3. 21. Connectors mounted between two balloons, initially covered or non-covered by a sheath, wherein the balloons act principally to bring the engagement members into contact with the apposing lumens; however, the two balloons may further act to dilate and further deploy the connector within the channel.
4. 26. Two piece connectors, such as the rivet device shown in Figure 6, may be deployable via two members mounted over a central core capable of

-41-

moving towards each other such that the resultant force acts to engage the inner aspect of the two rivet components, fixing them in apposition.

5. 5. Delivery mechanisms which hold the connector in a compressed state within a sheath and deploy the connector through the relative movement of an inner push-rod mechanism, allowing it to deploy in a first partially expanded state, and then to a fully expanded state.
- 10 6. 10. Delivery of connectors which may be rotationally inserted into the tissue, expanding it as it is advanced into position, and then disengaged, allowing the connector to remain anchored within the channel that was partially enhanced by the delivery mechanism.
- 15 7. 15. Delivery mechanisms which utilize some form of thermal, electrical, fluid or chemical means to induce a conformational change in the connector upon proper positioning in the channel.
- 20 Examples of suitable delivery catheters for implanting connector apparatus 10 of the present invention are shown in Figures 14a-14d.

Figure 14a shows a withdrawable sheath type delivery catheter 100a comprising an elongate inner member 102 having a connector apparatus 10 of the present invention mounted thereon, and a surrounding retractable outer sheath 104. The connector apparatus 10 in this embodiment is preferably self-expanding or formed of shape memory material which will radially expand when warmed to body temperature. When the sheath 104 is fully advanced over the connector apparatus 10, the sheath will radially constrain and hold the connector apparatus 10 in the desired radially compact configuration. After the catheter 100a has been advanced to the desired location, the sheath 104 may then be retracted (or alternatively the inner member 102 may be advanced) thereby removing the

-42-

surrounding constraint from the connector apparatus 10 such that the connector apparatus 10 may radially expand and become implanted in the desired location.

Figure 14b shows a balloon delivery catheter 100b comprising a tubular catheter body 106 and an elongate member 108 having an inflatable balloon 110 formed thereon. The connector apparatus 10 is initially mounted on the deflated balloon 110 with the connector apparatus 10 in its radially compact configuration.

5 After the catheter 100b has been advanced to the desired implantation site, the catheter 106 is withdrawn (or the inner member 108 is advanced) and the balloon is inflated so as to radially expand the connector apparatus 10 and to cause the connector

10 15 apparatus to become implanted at its desired implantation site.

Figure 14c shows a push rod type delivery catheter 100c comprising an outer tubular sheath 112 and an advanceable push rod 114. The connector apparatus 10 is initially placed in the lumen of the catheter sheath 112, ahead of the distal end of the push rod 114, with the connector apparatus 10 in its radially compact configuration. After the catheter 100c has been advanced to the desired implantation site the catheter 112 may be retracted (or the push rod 114 may be advanced) to expel the connector apparatus 10 out of the distal end of the catheter. In this manner, the connector apparatus 10 is relieved of any surrounding constraint and is permitted to radially expand and become implanted in the desired implantation site. It will be appreciated that this embodiment is particularly suitable for self-expanding embodiments of the connector apparatus 10 or those formed of shape memory material which will expand upon warming to body temperature. A more detailed description of this push rod type of delivery catheter is set forth in parent

20 25 30 35

-43-

application Serial No. 08/730,327, filed on October 11, 1996.

Figure 14d shows a slider sheath type delivery 100d. This device comprises an inner member 120 upon 5 which the connector apparatus 10 is mounted in its radially compact configuration. Proximal and distal sheaths 122a 122b are initially drawn together such that the distal end of the proximal sheath member 122a is in abutment with the proximal end of the distal 10 sheath member 122b, thereby covering and providing an enclosure or constraint about the radially collapsed connector apparatus 10. After the catheter 100b has been advanced to the desired implantation site, one or both of the proximal and distal sheath member 122a, 15 122b is/are moved away from the other so as to expose the radially compact connector apparatus 10, as shown in Figure 14b. In embodiments where the connector apparatus 10 is self-expanding or formed of shape memory material which will expand upon warming to body 20 temperature, such opening of the slider sheaths 122a, 122b will allow the connector apparatus 10 to expand and become implanted at its desired implantation site. In other embodiments wherein the connector apparatus 10 is formed of plastically deformable material, the 25 radial expansion member such as an inflatable balloon will be mounted on the inner member 120 beneath the radially compact connector apparatus 10. Such radial expansion or balloon may then be radially expanded (e.g., inflated) to radially expand and plastically 30 deform the connector apparatus 10, as desired.

Figure 14e shows a rotatable delivery catheter 100e which comprises an elongate member 130 which is in itself rotatable, or which is provided with a rotatable distal portion. The connector apparatus 10 is mounted 35 upon the distal portion of the elongate member 130, as shown. After the elongate member 130 has been advanced to a position adjacent the desired implantation site,

-44-

the elongate member 130 or the distal portion thereof is rotated, and the elongate member 130 is further advanced so as to rotatably drive and advance the connector apparatus 10 into the desired implantation site. It will be appreciated that this embodiment is particularly useable for connector apparatus 10 which are not radially expandable, and/or those having helical or spiral ribs on the outer surface thereof (e.g., Figure 11c) and/or for those having a leading edge which is sharpened or otherwise adapted to cut tissue so as to bore and form or enlarge the passageway as the connector apparatus is advanced.

These additional connector delivery catheters shown in Figures 14a-14e are examples of the types of delivery catheter devices which may be utilized, in addition to the double balloon catheter shown in Figures 3''', 4''' and 5'', and described more fully hereabove.

20 xv. Connector Apparatus Which Include Tissue Puncturing Connecting Portions Such That The Connecting Portions May Reside Outside of The Fluid Flow Passageway

Figures 15a-15a' show a modified rivet type connector apparatus 10e''', of the type previously described and claimed in United States Patent Application Serial No. 08/730,327. This connector apparatus 10e''' comprises first and second annular engagement members 600, 602, and a plurality of connecting members 604 which extend from first engagement member 600 and which are adapted to engage and connect to receiving aperture 606 formed in the second engagement member 602. As shown in Figure 9a and 9a', the connector member 604 may be capable of penetrating through the tissue, and may be situated such that they will pass through the walls of the first and second blood vessels BV₁, BV₂ and through any intervening interstitial tissue such that the connector

-45-

members 604 will lay outside of the previously formed passageway or channel, and outside of the openings formed in the respective first and second blood vessels BV₁, BV₂.

5 These drawings illustrate that the connector portion of the connector apparatus 10 need not extend through or reside within the fluid flow passageway, but actually may protrude through intervening tissue and reside outboard of the passageway, as shown.

10 These delivery devices are generally capable of being advanced over a guide wire into the channel and may assist passively or actively in the proper deployment of the connector. Further it should be understood that various radiopaque or imageable markers 15 may be placed in important locations on the delivery mechanism to permit proper placement or monitoring of placement during deployment. Further, it is also possible that various recapturing mechanisms such as thread(s), hood(s) or other capturing or securing means 20 may be provided to allow for the reversible deployment of the connector in the instance where it was found to be improperly placed.

The invention has been described hereabove with reference to certain presently preferred embodiments 25 only, and no effort has been made to exhaustively describe and show all possible embodiments in which the invention may take physical form. Indeed, numerous alterations, modifications and changes may be made to the above-described embodiments without departing from 30 the spirit and scope of the invention. For example, specific elements or attributes of one embodiment may be incorporated into any or all of the other embodiments shown in the drawings, and may be interchanged or recombined in any possible 35 combinations, and all such modifications and combinations of the elements and components of the

-46-

invention described herein are intended to be within
the scope of the following claims.

WHAT IS CLAIMED IS:

1. An apparatus for connecting a first opening formed in a first anatomical structure to a second opening formed in a second anatomical structure said 5 first anatomical structure having an inner space which is defined at least in part by a first inner surface, and said second anatomical structure having an inner space which is defined at least in part by a second inner surface, said apparatus comprising:
 - 10 a) a first engagement portion which is engageable with the first anatomical structure adjacent the first opening formed therein;
 - b) a second engagement portion which is engageable with the second anatomical structure, 15 adjacent the second opening formed therein;
 - c) a connecting portion which connects said first engagement portion and said second engagement portion, said connecting portion being configured to hold said first and second openings 20 relative to each other.
2. The apparatus of Claim 1 wherein said connecting portion is a tubular member.
3. The apparatus of Claim 1 wherein said connecting portion is a wire member.
- 25 4. The apparatus of Claim 3 wherein said wire member is of a helical configuration.
5. The apparatus of Claim 1 wherein said connecting portion comprises a frame which will maintain an open passageway through surrounding tissue.
- 30 6. The apparatus of Claim 1 wherein said connecting portion is a mesh tube.
7. The apparatus of Claim 1 wherein said first engagement portion is a splayable member which is initially maintained in a non-splayed configuration 35 and, after being positioned adjacent the first opening formed in the first anatomical structure, is convertible to a splayed configuration wherein said

-48-

first engagement member will engage the inner wall of the first anatomical structure adjacent the first opening formed therein.

8. The apparatus of Claim 1 wherein said second engagement portion is a splayable member is initially maintained in a non-splayed configuration and, after being positioned adjacent the second opening formed in the second anatomical structure, is convertible to a splayed configuration wherein said second engagement member will engage the inner wall of the second anatomical structure adjacent the second opening formed therein.

9. The apparatus of Claim 7 wherein said first engagement member is self-splaying and resiliently biased to its splayed configuration.

10. The apparatus of Claim 8 wherein said second engagement member is self-splaying and resiliently biased to its splayed configuration.

11. The apparatus of Claim 7 wherein said first engagement portion is plastically deformable and is initially formed in its non-splayed configuration, and is subsequently deformable to its splayed configuration by exertion of pressure against said engagement member.

12. The apparatus of Claim 8 wherein said second engagement portion is plastically deformable and is initially formed in its non-splayed configuration, and is subsequently deformable to its splayed configuration by exertion of pressure against said engagement member.

13. The apparatus of Claim 1 wherein said apparatus is initially deployable in a radially compact configuration, said apparatus being subsequently radially expandable to an operative configuration wherein at least said first and second engagement portions will abut against and engage the adjacent surfaces of the first and second anatomical structures.

-49-

14. The apparatus of Claim 13 wherein said apparatus is self-expanding and resiliently biased to its operative configuration.

15. The apparatus of Claim 13 wherein said 5 apparatus is plastically formable and is initially formed in its radially compact configuration, and is subsequently deformable to its operative configuration by exertion of radial pressure upon said apparatus.

16. The apparatus of Claim 1 wherein said 10 apparatus is a hyperboloidal helical coil.

17. The apparatus of Claim 16 wherein said 15 hyperboloidal helical coil is formed of a multiplicity of adjacent convolutions of wire, and wherein at least some of said adjacent convolutions are fused to one another.

18. The apparatus of Claim 1 wherein said first 20 and second engagement portions comprise frusto-conical helical coils having outer and inner ends, the outer ends of said helical coils being larger in diameter than the inner ends thereof.

19. The apparatus of Claim 18 wherein said connecting portion of said apparatus comprises a tubular member mounted between and connecting the inner ends of said frusto-conical helical coils.

20. The apparatus of Claim 1 wherein said 25 apparatus is a tube having inwardly arched side walls such that the ends of the tube are of larger diameter than the middle of the tube, said ends of the tube thereby forming said first and second engagement portions, and said middle of the tube thereby forming 30 said connecting portion.

21. The apparatus of Claim 20 further comprising: 35 at least one splayable engagement member formed on each end of the tube.

22. The apparatus of Claim 21 wherein said at 40 least one splayable engagement member is self-splaying

-50-

and resiliently biased to an outwardly splayed configuration.

23. The apparatus of Claim 21 wherein said at least one engagement member is plastically deformable, 5 and initially formed in a non-splayed configuration but subsequently deformable by exertion of outwardly directed pressure thereagainst.

24. The apparatus of Claim 20 wherein said tube is a solid tube.

10 25. The apparatus of Claim 20 wherein said tube is mesh tube.

26. The apparatus of Claim 20 wherein said tube is formed of a material selected from the group of materials consisting of:

15 a helical wire coil;
a helical filament coil;
wire mesh;
a shape memory alloy;
plastic;
20 metal;
woven fabric;
elastic material; and,
elastomeric material.

25 27. The apparatus of Claim 1 wherein said apparatus comprises a plastic structure wherein the connecting portion comprises a tube, and wherein a first and second engagement portions comprise projections which extend laterally outward from opposite ends of said tube.

30 28. The apparatus of Claim 1 wherein said apparatus comprises a wire clip, wherein said first and second engagement portions comprise wire projections which extend laterally outward from the center of the clip, and wherein said connecting portion comprises 35 traversing segments of wire which extend between said projections.

-51-

29. The apparatus of Claim 1 wherein said apparatus comprises an elongate member having a series of generally sinusoidal bends formed therein, and first and second ends, the first and second ends of said wire member being joined to one another to form a ring, and at least some of said sinusoidal bends being turned outwardly therefrom to form projections which extend outwardly from said ring, said projections thereby forming said first and second engagement portions, and 10 said ring thereby forming said connecting portion.

30. The apparatus of Claim 29 wherein said sinusoidal bends include a plurality of first sinusoidal bends of a first amplitude, and a plurality of second sinusoidal bends of a second amplitude, said 15 second amplitude being larger than said first amplitude, said second sinusoidal bends of said second amplitude being bent outwardly to form said projections, and said first sinusoidal bends of said first amplitude remaining without outward bending so as 20 to form said ring.

31. The apparatus of Claim 1 wherein said apparatus comprises a triplet coil connector comprising:

25 a first helical coil having a first longitudinal axis, a second helical coil having a second longitudinal axis which is not parallel to the first longitudinal axis, and a third helical coil having a third longitudinal axis, said third longitudinal axis being perpendicular to said 30 second longitudinal axis but spaced apart from said first longitudinal axis;

35 said triplet coil connector being thereby implantable within the body such that the first helical coil is within the inner space of the first anatomical structure, said third helical coil is within the inner space of the second anatomical structure, and said second helical coil

-52-

extends between said first and second openings in said first and second anatomical structures.

32. The apparatus of Claim 31 wherein said first, second, and third coil members are formed of helically wound wire.

5 33. The apparatus of Claim 31 wherein said first, second, and third coil members are formed of helically wound filament.

34. The apparatus of Claim 1 wherein said 10 connector apparatus is a flanged tube connector wherein said connecting portion comprises a tube, and wherein said first and second engagement portions comprise semi-cylindrically shaped flanges which extend laterally outward from opposite ends of the said tube.

15 35. The apparatus of Claim 34 wherein said flanged tube connector is formed by a method comprising the steps of:

20 a) providing a tube having a longitudinal axis, a cylindrical side wall disposed about said longitudinal axis, first and second ends, and a hollow lumen extending longitudinally therethrough;

25 b) forming first and second rectangular notches at directly opposite locations in the first end of said tube, said rectangular notches having side edges which are parallel to said longitudinal axis, and an end which is perpendicular to said longitudinal axis;

30 c) forming third and fourth rectangular notches at directly opposite locations in the second end of said tube, said rectangular notches having side edges which are parallel to said longitudinal axis, and an end which is perpendicular to said longitudinal axis;

35 d) forming first and second generally arcuate notches at directly opposite locations in the cylindrical side wall of the tube, in

-53-

alignment with the ends of the first and second rectangular notches;

5 e) forming third and fourth generally arcuate notches at directly opposite locations in the cylindrical side wall of the tube, in alignment with the ends of the third and fourth rectangular notches; and,

10 f) outwardly bending the remaining cylindrical side walls of the tube adjacent said rectangular notches such that said generally arcuate notches become substantially closed, and said outwardly bent portions of the side wall form semi-cylindrical flanges which protrude outwardly from opposite ends of the remaining mid-portion of 15 the tube, generally perpendicular to said longitudinal axis.

36. The apparatus of Claim 1 wherein said connecting portion is configured to extend through and reside within a passageway formed between said first 20 and second openings.

37. The apparatus of Claim 1 wherein said connecting portion is constructed to penetrate through tissue and is positioned to reside within surrounding tissue and outboard of a passageway which has been 25 formed between the first and second openings.

38. The apparatus of Claim 1 wherein said apparatus is adapted to transmit energy to tissue with which the apparatus comes into contact, thereby providing an energy-mediated treatment to said tissue.

30 39. The apparatus of Claim 1 wherein said first and second engagement portions comprise annular members, and wherein said connecting portion comprises:

35 at least one connector member formed on said first engagement portion and adapted to insert into an engaged said second engagement portion when said first and second engagement portions are moved toward one another.

-54-

40. The apparatus of Claim 39 wherein said connector portion comprises at least one elongate member.

41. The connector apparatus of Claim 1 wherein 5 said apparatus further comprises at least one magnet to facilitate connection of the first engagement portion to the second engagement portion.

42. The connector apparatus of Claim 1 wherein 10 said connecting portion comprises scaffolding to deter in growth into the passageway formed between the first and second anatomical structure.

43. The connector apparatus of Claim 1 wherein 15 said connector has a leading edge, and wherein said leading edge is adapted to sever tissue as said connector is advanced.

44. The connector apparatus of Claim 1 wherein said connector has an outer covering which is selected from the group of outer coverings consisting of:

20 a synthetic tube graft;
a natural tube graft;
a chemical coating;
an antithrombogenic coating;
a thrombolytic coating; and,
an antimicrobial coating.

25 45. The connector apparatus of Claim 1 wherein said connector further comprises at least one radioactive material to deter tissue ingrowth following implantation.

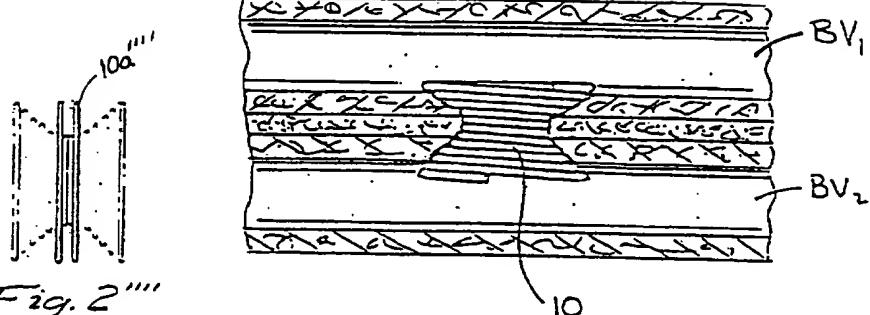
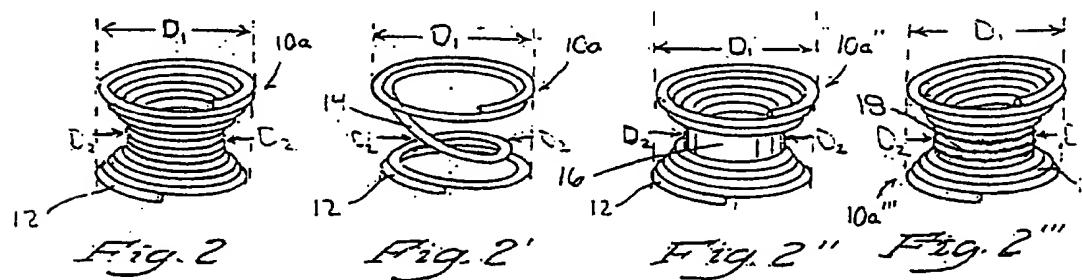
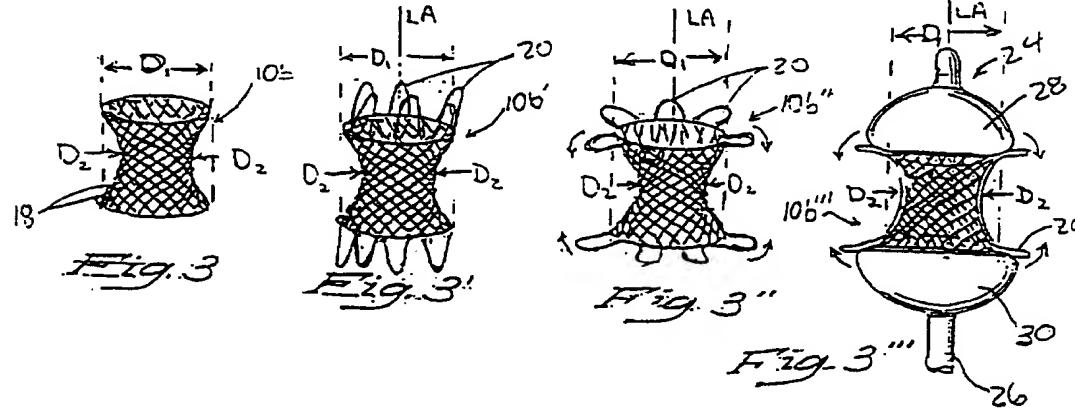
30 46. The connector apparatus of Claim 1 wherein said connecting portion is constructed to pull said first and second engagement portions toward one another.

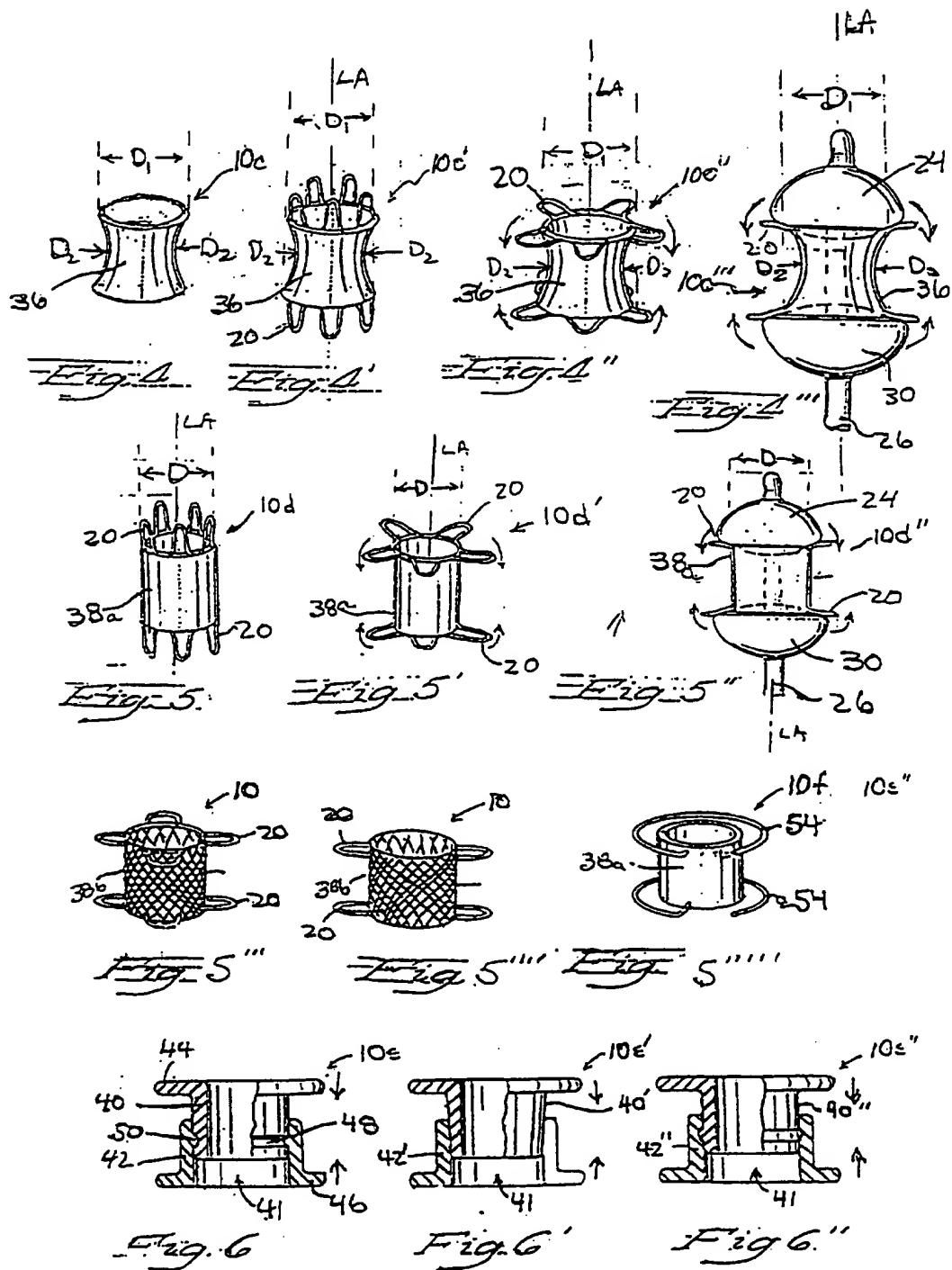
35 47. The connector apparatus of Claim 46 wherein said pulling of the first and second engagement members toward one another enables the connector apparatus to form connections between anatomical structures which are separated by varying distances.

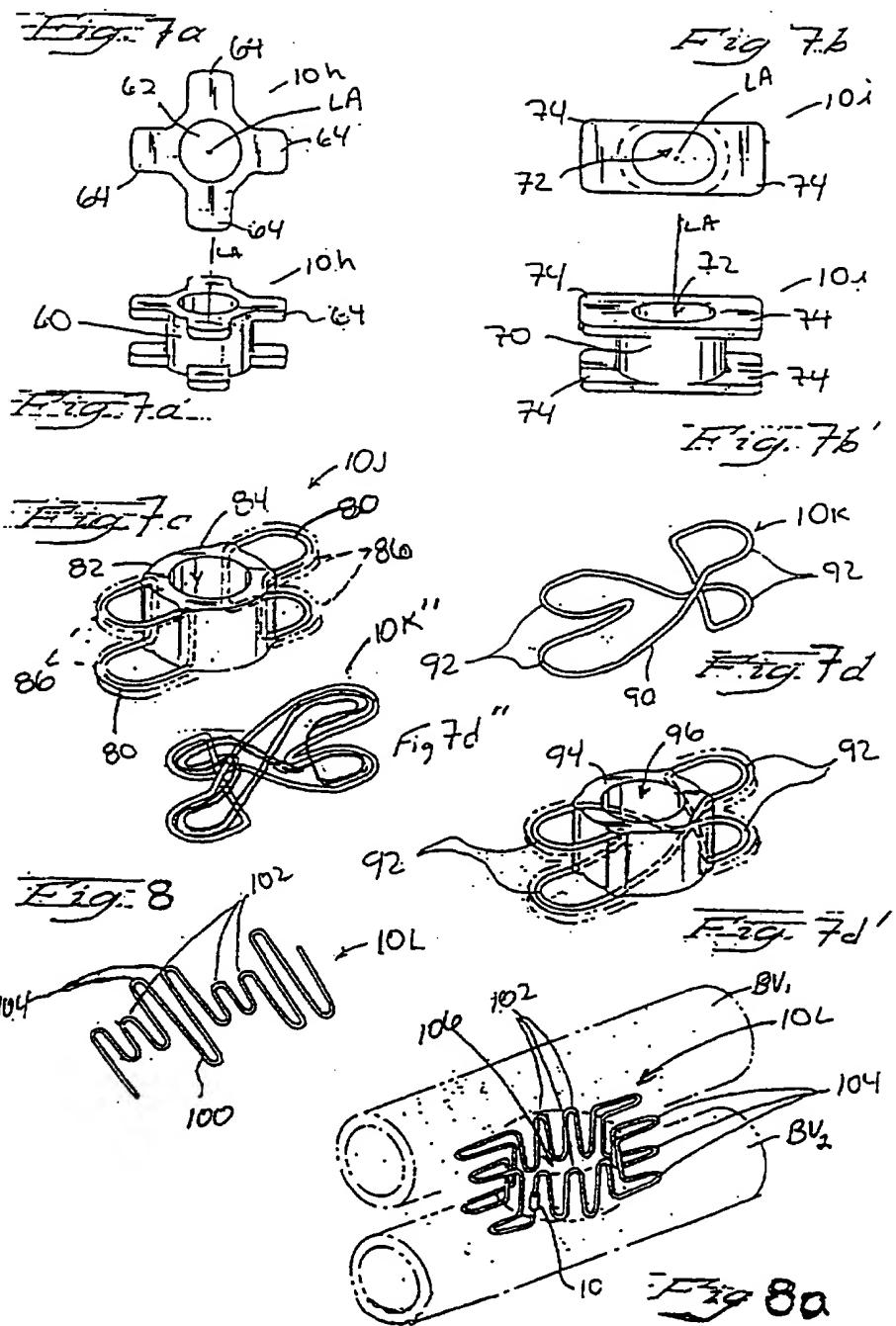
-55-

48. The connector apparatus of Claim 46 wherein said pulling of the first and second engagement members toward one another serves to minimize the length of the channel wherein the connector apparatus is implanted.

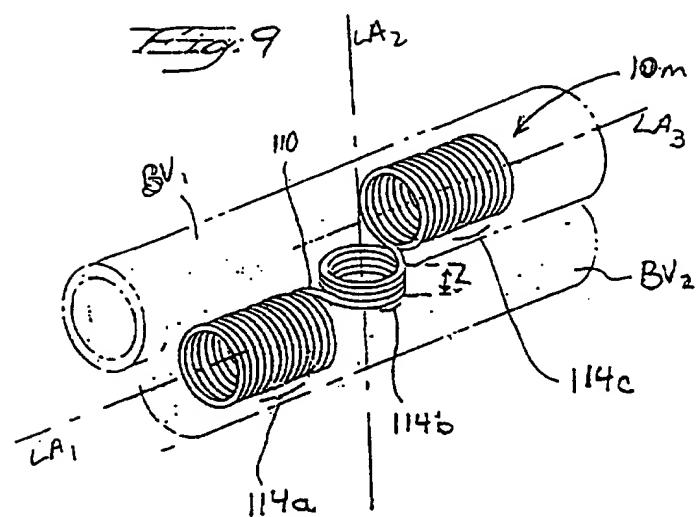
5 49. The connector apparatus of Claim 1 wherein the connecting portion of the apparatus is constructed to maintain a passageway of a predetermined minimum diameter between the first and second openings formed in the first and second anatomical structures.

Fig. 1Fig. 2'''Fig. 2Fig. 2'Fig. 2''Fig. 2'''Fig. 3Fig. 3'Fig. 3''Fig. 3'''





4/7



5/7

Fig. 10

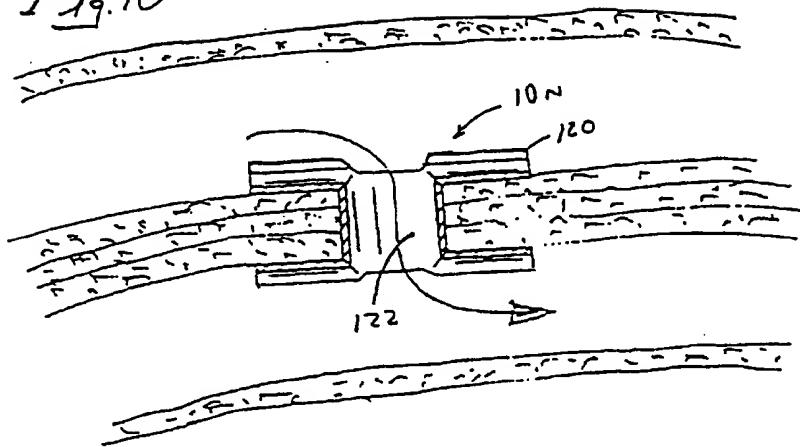


Fig. 10a

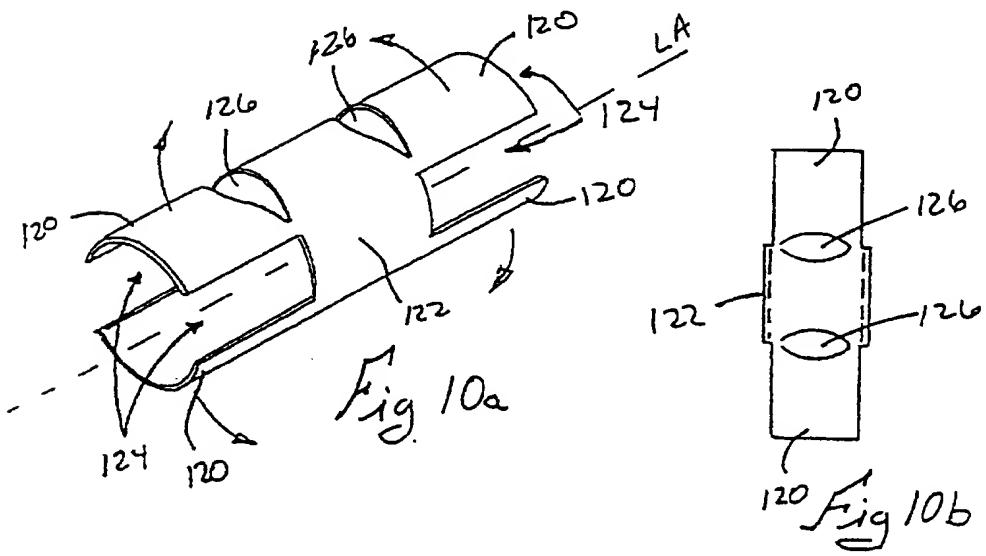


Fig. 10b

6/7

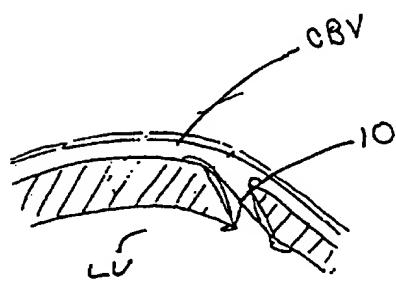
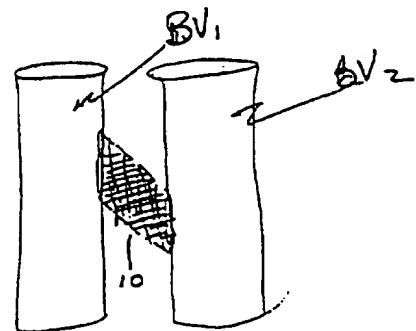
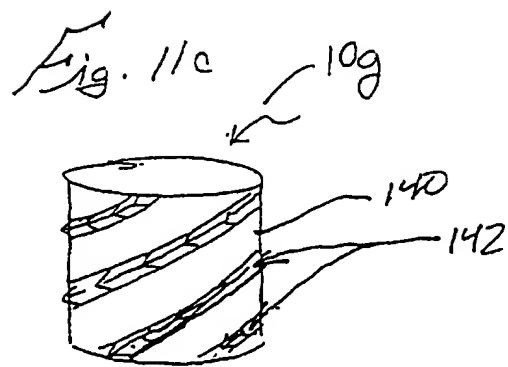
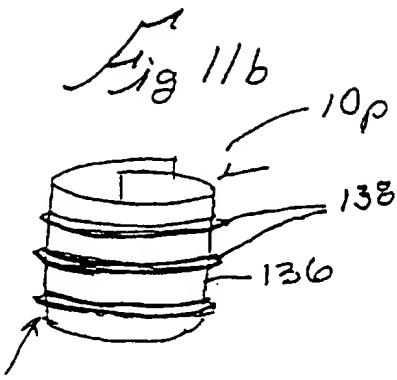
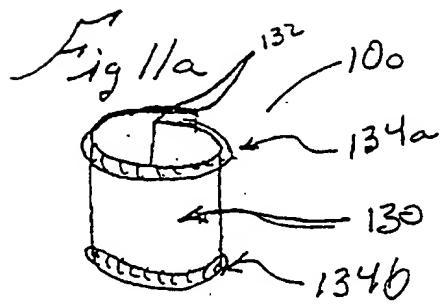
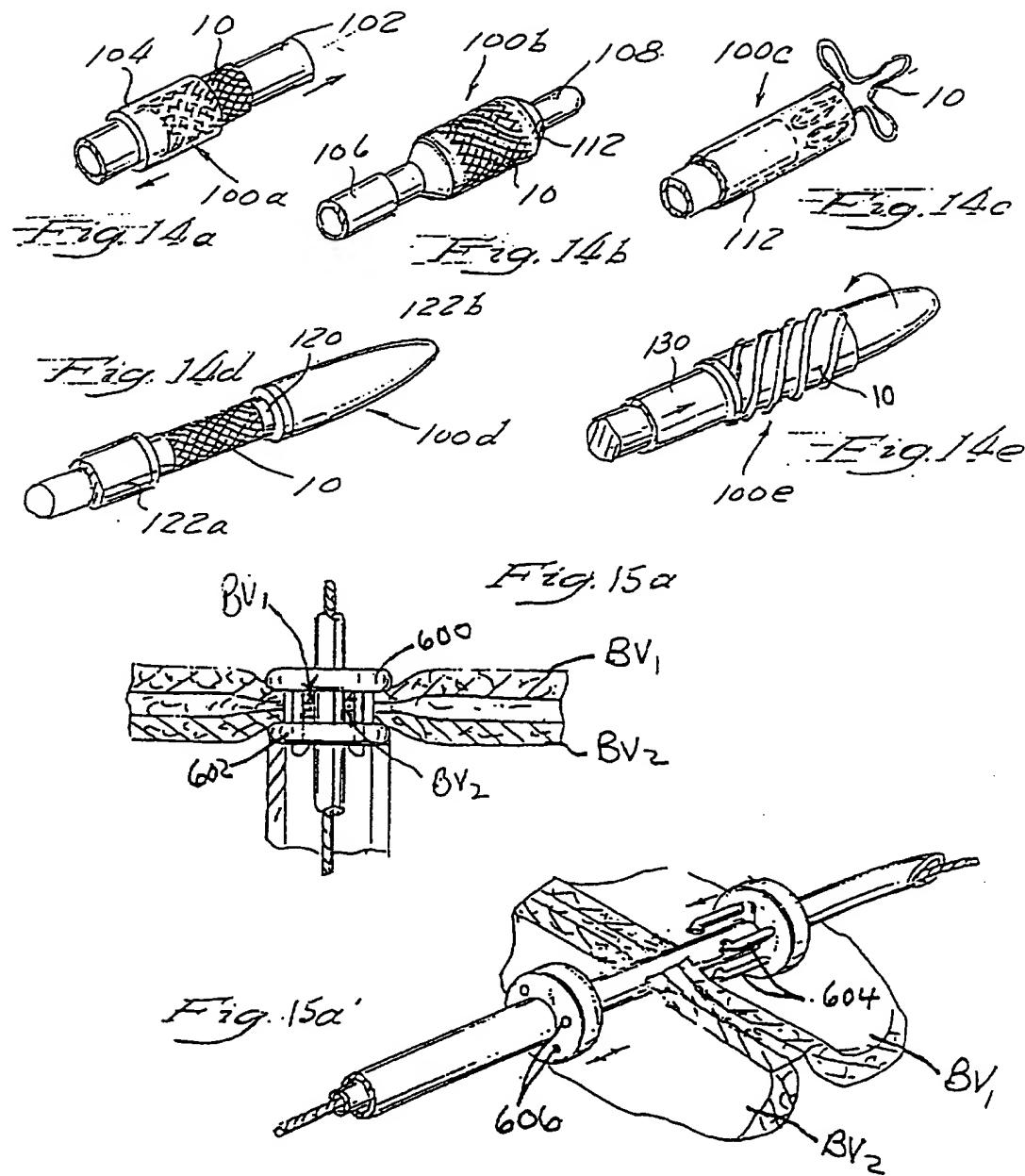


Fig 13

Fig 12

7/7



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/01468

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 29/00

US CL : 606/198

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/1, 108, 152-156, 192, 194, 195, 198, 200; 623/1, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,383,892 A (CARDON et al.) 24 January 1995, entire document.	1-45
X	US 5,466,242 A (MORI) 14 November 1995, entire document.	1-45

Further documents are listed in the continuation of Box C. See patent family annex.

Special categories of cited documents:		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"
"E"	earlier document published on or after the international filing date	"X"
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"
"O"	document referring to an oral disclosure, use, exhibition or other means	
"P"	document published prior to the international filing date but later than the priority date claimed	"&"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 MARCH 1997	02 JUN 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer WILLIAM LEWIS <i>W. Lewis</i>
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0060

THIS PAGE BLANK (USPTO)